9. (Four times amended) A process for increasing the lutein concentration in the circulating blood of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing from about 1 to from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

10. (Four times amended) A process for increasing immunoglobulin concentration in a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immunoglobulin increasing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of the animal.

11. (Four times amended) A process for increasing lymphocyte cells in a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective lymphocyte increasing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks presented herein, is respectfully requested. Claims 2, 12 and 14 are cancelled. Claims 1 and 9-11 are amended. The pending claims are claims 1 and 3-11. No new subject matter has been added. The amendments are made to clarify the claims, and they do not narrow the claims. Therefore, the amended claims are entitled to a full scope of equivalents.

Examiner Interview

Applicant's Representatives thank Examiner Wang for courtesies extended during the telephonic interview held on 4 March 2002. During the interview, the 35 U.S.C. § 103(a) rejection was discussed and its applicability to the pending claims. In addition, possible claim amendments

were discussed (see below).

The above account is believed to be a complete and accurate summary of the telephonic interview as required by 37 C.F.R. §1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication to Applicant's Representatives so that the interview summary can be amended or supplemented.

The 35 U.S.C. § 103(a) Rejections

The Examiner rejected claims 1-12 and 14 under 35 U.S.C. § 103(a) over Jyonouchi et al., Abstract No. 1994:321921 CAPLUS, in view of Anon., Accession No. 97:19:19144 BIOBUSINESS, Ito et al., which the Examiner asserts is U.S. Patent No. 5,993,714 but Applicant assumes the Examiner refers to U.S. Patent No. 5,937,790, Krinsky, Accession No. 91090021 MEDLINE, and further in view of page 11 of CRC Handbook of Toxicology, Derelanko and Hollinger, eds., the date of which the Examiner asserts is 1995 (see the Office Action mailed April 11, 2000). The Examiner further rejected claims 1-12 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Ito et al. As these rejections may be maintained with respect to the pending claims, they are respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations. The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. M.P.E.P. § 2142.

The claims, as amended, are directed to a process for enhancing immune response of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immune enhancing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed by said animal (claims 1 and 3-8); a process for increasing the lutein concentration in the

circulating blood of a companion animal consisting of a dog or cat (claim 9); a process for increasing immunoglobulin concentration in a companion animal consisting of a dog or cat (claim 10); and a process for increasing lymphocyte cells in a companion animal consisting of a dog or cat (claim 11).

I. *Prima facie obviousness has not been established*

Jyonouchi et al., Abstract No. 1994:321921 CAPLUS, corresponds to Jyonouchi et al., Nutr. Cancer, 21, 47-58, (1994) (referred to hereafter as the Jyonouchi et al. article). The Jyonouchi et al. article describes studies undertaken to elucidate the effect of carotenoids on humoral immune responses in mice (see abstract and page 48 of the Jyonouchi et al. article). To measure *in vitro* antibody production, plaque formation cell (PFC) assays were conducted on spleen cell cultures prepared from the mice. T-dependent antigens (TD-Ag), i.e., sheep red blood cells (SRBC) and Keyhole limpet hemocyanin modified with trinitrophenol (TNP-KLH), and T-independent antigen (TI-Ag), i.e., lipopolysaccharide modified with trintrophenol (TNP-LPS), were added to splenocyte cultures in the presence of lutein, astaxanthin, and β-carotene (page 48-49). *In vivo* antibody production was determined by administering TD-Ag and TI-Ag to mice by intraperitoneal (IP) injection. An hour prior to antigen challenge, $5x10^{-10}$ mol/mouse of either lutein, astaxanthin, or β-carotene was also injected IP into the mice (page 52). PFC assays were conducted on splenocyte suspensions prepared from spleens harvested from these animals.

In the *in vitro* antibody production assays, culturing splenocytes with lutein following SRBC-priming was found to enhance PFC formation, but did not result in an increase in IgM or IgG concentrations in culture supernatant (Table 1). Moreover, *in vitro* antibody production was not enhanced by lutein in the TI-Ag-primed cells (page 55). Lutein did not significantly enhance PFC formation or IgM concentrations in the TNP-LPS-primed cells (Table 2). In fact, Jyonouchi et al. reveal that lutein, as well as astaxanthin and β-carotene, "did not augment antibody production in response to a TI-Ag, but rather suppressed it" (emphasis added, page 56). Jyonouchi et al. further state that the carotenoids tested "did not significantly increase total IgM or IgG concentrations in the culture supernatant" (page 56). Thus, the present claims are not made obvious in view of Jyonouchi et al.

Ito et al. do not remedy the deficiencies of Jyonouchi et al. Ito et al. discuss anti-stress

agents, e.g., L-ascorbic acid-2-phosphoric acid, salts thereof, and L-ascorbic acid-2-glucoside, as active ingredients of a feed composition that reduces the growth inhibition or mortatility in animals (abstract). Ito et al. relate that antioxidants, such as dl-α-tocopherol, dl-α-tocopheryl acetate, vitamin E a derivative thereof, erythorbic acid, tea extract, polyphenols, ethoxychin, carotenoids such as astaxanthin, organic acids such as citric acid and glycine, phosphoric acids such as phosphoric acid and metaphosphoric acid, stabilized L-ascorbic acids such as L-ascorbic sulfate and L-ascorbic palmitate, carotene, lutein, α-tocopherol, SOD, glutathione and catechins, can be administered in conjunction with the anti-stress agents. Ito et al. measure the effect of five food compositions, one of which contains β-carotene, lutein, and astaxanthin, on cattle and swine by measuring the presence of lactate dehydrogenase (LDH), malate dehdrogenase (MDH), aspartate aminotransferase (AspAT) and stress proteins in the blood plasma of the animals.

The Examiner asserts that it is *prima facie* obvious to "employ lutein in cat or dog" for improving immune response, since (a) lutein has been suggested to be similarly useful in humans; (b) lutein has been "proven" to be effective in improving the immune response in the mouse; and (c) feeding an animal with lutein is generally known (page 2 of the Advisory Action).

Regarding (a), above, Applicant's Representatives are unable to find, in the cited documents, any report that lutein has been suggested to be effective in improving the immune response of humans. Therefore, the Examiner's characterization of the documents is believed to be incorrect. Additionally, the present claims are directed, *inter alia*, to a process for enhancing the immune response of a dog or a cat, not a human.

As for (b) and (c), above, there is no motivation to combine the teachings of Ito et al., which are directed to methods and compositions for reducing stress in animals, with those of Jyonouchi et al., which relate to the impact IP administration of lutein has on the humoral immune response in mice. Moreover, the cited documents do not provide a reasonable expectation of success. As discussed above, Jyonouchi et al. describe assays in which the effect of lutein on the humoral immune response of the mouse was measured following IP administration of lutein, i.e., the lutein was injected in close proximity to the mouse's spleen. Based on this, the art worker would not have a reasonable expectation of success that the dietary administration of lutein to a companion animal would have any effect on the recipient animal's immune response. The Examiner is respectfully

requested to consider that IP administration of lutein is significantly different than the claimed methods, which are directed to processes comprising the step of feeding a diet containing lutein, and absorption of the lutein by the dog or cat. There is no suggestion in the cited documents that any of the beneficial effects recited by the claims would be achieved if lutein were fed to a cat or a dog. As the cited documents provide neither the requisite suggestion or motivation to combine the teachings to arrive at the claimed invention, nor a reasonable expectation of success that the claimed methods could be successfully practiced, Applicant respectfully submits that *prima facie* obviousness has not been established. Therefore, withdrawal of the 35 U.S.C. § 103(a) rejection is respectfully requested.

Further regarding (c), above, the Examiner is respectfully requested to consider that a "new use" of a composition is clearly patentable subject matter 35 U.S.C. § 100(b). The present claims are directed to previously unknown uses for a composition comprising lutein, which are based on the discovery that, *inter alia*, dietary administration of lutein enhances the immune response of companion animals. 35 U.S.C. § 101. To render such a claim obvious, the obviousness of the claimed result must be apparent to one of skill in the art from the prior art, viewed without the benefit of knowledge of Applicant's invention. Thus, even if dietary administration of lutein is "generally known", there is nothing in the cited art to suggest that the dietary administration of lutein would have any beneficial effect on the immune response of a cat or a dog. In Ex parte Levengood, 28 USPQ2d 1300 (Bd. App. 1993) (a copy is enclosed herewith), the Examiner noted that because all aspects of the invention were well known to the art, the claimed method was "well within the ordinary skill of the art at the time the claimed invention was made." The Board reversed the obviousness rejection, stating

> at best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness. See Orthokinetics Inc. v. Safety Travel Chairs Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). That which is within the capabilities of one skilled in the art is not synonymous with obviousness. Ex parte Gerlach, 212 USPQ 471 (Bd. App. 1980). See also footnote 16 of Panduit Corp. v. Dennison Mfg. Co., 774 F.2d 1082, 1092, 227 USPQ 337, 343 (Fed. Cir. 1985).

The Examiner is also respectfully requested to note that the fact that lutein may previously have been suggested as a possible ingredient in a food stuff does not render the claimed use of lutein obvious in the absence of a suggestion that the beneficial therapeutic results recited by the claimed methods would occur. None of the cited documents teach or suggest that oral administration of lutein would have any effect on an animal's immune system or would increase the concentration of lutein in an animal's blood. Thus, is respectfully submitted that *prima facie* obvious has not been established.

Therefore, withdrawal of the 35 U.S.C. § 103(a) rejection is respectfully requested.

II. *The present claims are not directed to functional limitations of a known process*

In the Office Action mailed April 17, 2001, the Examiner rejected claims 1-12 and 14 under 35 U.S.C. § 103(a) as obvious the Jyonouchi et al., abstract, in view of Anon., Ito et al., Krinsky, and further in view of page 11 of CRC Handbook of Toxicology, asserting that

> the instant claims are directed to effecting a biochemical pathway with old and well-known compounds. It is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter.

(page 6 of the Office Action mailed April 17, 2001). In support of this proposition, the Examiner cites In re Swinehart, 169 U.S.P.Q. 226, wherein the court stated

> it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art

169 U.S.P.Q. at 229. The Examiner reiterated this position during the telephonic interview, *supra*, and alleged that because Ito et al. teach feeding an animal a diet comprising lutein, and because the present claims merely recite "functional limitations" of a known process, the "ultimate utility (feeding lutein to dog or cat) for the claimed compounds is old and well known" (page 6 of the Office Action dated April 17, 2001).

Applicant respectfully submits that In re Swinehart, a case involving the propriety of a claim reciting functional language under 35 U.S.C. § 112, can be distinguished from the instant facts. For example, the pending claims are not rejected under 35 U.S.C. § 112.

In In re Swinehart and Sfiligoj, both the examiner and the board asserted that the phrase "transparent to infra-red rays" in a claim reciting

> a new composition of matter, transparent to infra-red rays and resistant to thermal shock, the same being a solidified melt of two components present in proportion approximately eutectic, one of said components being BaF_2 and the other being CaF_2

was improperly functional, rendering the claim indefinite under 35 U.S.C. § 112. 169 U.S.P.Q. at 227. The CCPA reversed, holding that there is nothing "intrinsically wrong" with a claim reciting functional language. 169 U.S.P.Q. at 228. The court stated that because the Patent Office "possesses the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon", the

> fear that an applicant will attempt to distinguish over a reference disclosure by emphasizing a property or function not mentioned by the reference and thereby assert that [the] claimed subject matter is novel is ... misplaced.

169 U.S.P.Q. at 228-229. The court emphasized that the only proper grounds for rejecting a claim under 35 U.S.C. § 112 are (1) where a claim does not recite precise and definite language; and (2) where a claim recites language that is broader than the scope of the disclosure. 169 U.S.P.Q. at 229.

Thus, In re Swinehart and Sfiligoj is readily distinguished from the present situation, wherein Applicant's claims are not directed towards "functional limitations", but, as discussed above, are directed towards a "new use' for a dietary composition comprising lutein.

Moreover, Applicant respectfully submits that the instant claims are directed towards a "new use" for a composition and that they do not simply relate to a mechanism for a previously known use. Hence, the claims are patentable. 35 U.S.C. §101 and MPEP 2112.02. During the telephonic interview, the Examiner suggested that if Applicant's claims were directed to a "new use" for lutein, the claims should recite a specific population for treatment. The Examiner suggested that it might by helpful if the claims were amended to recite "in need of such treatment". Applicant thanks the Examiner for the suggestion, and has amended the claims accordingly.

Furthermore, the Examiner is respectfully requested to note that inherency and obviousness

are entirely different questions. In re Shetty, 195 U.S.P.Q. 753, 757 (C.C.P.A. 1977), citing In re Spormann, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966). Obviousness cannot be predicated on what is unknown. Id. See also, Ex parte McQueen, 123 U.S.P.Q. 37 (Bd. App. 1958) (the inherency must be certain to one of skill in the art). Prior to Applicant's discovery, it was unknown that feeding dogs or cats a diet comprising lutein would have any beneficial impact on the dog's or cat's immune response.

Thus, withdrawal of the 35 U.S.C. § 103(a) rejection of the claims is respectfully requested.

III. *Claim 11*

In addition to the remarks above, the following remarks are also provided to support the patentability of claim 11.

Claim 11 is directed to a process for increasing lymphocyte cells in a dog or a cat comprising feeding a diet containing lutein.

As argued previously, Jyonouchi et al. relate that lutein may affect the humoral immune response of a mouse spleen following IP administration of lutein, and Ito et al. relate that lutein can be used as an anti-oxidant in a food composition for reducing stress in animals. However, there is nothing in any of the cited documents that teach or suggest that oral administration of lutein would have any impact on increasing lymphocyte cells in a dog or a cat. As discussed above, Ito et al. measured LDH, MDH, AspAT and stress proteins in the plasma of animals following dietary administration of a food composition that contained anti-stress agents as well as antioxidants such as lutein. There is nothing in Ito et al. that teaches or suggests the impact of Ito et al.'s food composition on lymphocyte cells in a dog or a cat. Furthermore, Jyonouchi et al. relate that "no enhancing action" was observed following *in vitro* administration of lutein on antibody production of mouse splenocytes in response to TNP-LPS, and lutein "did not significantly alter the numbers of IgM-secreting cells *in vivo* in response to TNP-LPS" (Jyonouchi et al. at pages 52 and 54). In fact, Jyonouchi et al. conclude that "[carotenoid] action on humoral immune responses may be selective and dependent upon the type of antigen" (emphasis added, page 56). Thus, one of ordinary skill in the art would not conclude from Jyonouchi et al. that dietary administration of lutein would increase lymphocyte cells in a dog or a cat. Therefore, claim 11 is not obvious in view of the cited

documents.

Hence, withdrawal of the 35 U.S.C. § 103(a) rejection of claim 11 is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-371-2106) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,
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Date 14 March 2002 By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Box AF, Commissioner of Patents, Washington, D.C. 20231, on this 14th day of March, 2002.

Candis B. Buending
Name

Signature

CLEAN VERSION OF PENDING CLAIMS

COPY OF PAPERS ORIGINALLY FILED

E1

1. (Five times amended) A process for enhancing immune response of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immune enhancing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed by said animal.

3. A process as claimed in claim 1 in which said diet includes from about 2 to about 315 mg lutein per kg of diet.

4. A process as claimed in claim 1 wherein said companion animal is a dog.

5. A process as claimed in claim 4 in which said diet includes from about 5 to about 20 mg/day of lutein.

6. A process as claimed in claim 1 wherein said companion animal is a cat.

7. A process as claimed in claim 6 in which said diet includes from about 5 to about 10 mg/day of lutein.

8. A process as claimed in claim 1 in which said diet comprises about 20 to 40% crude protein, about 4 to 30% fat, and about 4 to 20% total dietary fiber.

E2

9. (Four times amended) A process for increasing the lutein concentration in the circulating blood of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing from about 1 to from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

10. (Four times amended) A process for increasing immunoglobulin concentration in a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immunoglobulin increasing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of the animal.

11. (Four times amended) A process for increasing lymphocyte cells in a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective lymphocyte increasing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Levengood

No. 92-3654

Decided April 22, 1993
Released August 6, 1993

PATENTS

1. Patentability/Validity — Obviousness — Combining references (§115.0905)

Motivation for combining prior art references need not be explicitly found in references themselves, and examiner may provide explanation based on logic and sound scientific reasoning that will support holding of obviousness; fact that invention's theoretical mechanism can be reconstructed and explained by means of logic and sound scientific reasoning does not, however, support obviousness determination unless that logic and reasoning would supply sufficient impetus to have led one of ordinary skill in art to combine references to make claimed invention, and thus examiner cannot establish obviousness by locating references which describe various aspects of applicant's invention unless examiner also provides evidence of motivating force which would impel person skilled in art to do what applicant has done.

Appeal from final rejection of claims in application for patent (Elizabeth C. Weimar, supervisory patent examiner; Gary Benzion, examiner).

Patent application of William C. Levengood, serial no. 539,302, filed June 16, 1990, which is a continuation of application serial no. 363,451, filed June 6, 1989, now abandoned; which is a continuation of application serial no. 907,858, filed Sept. 15, 1986, now abandoned; which is a continuation-in-part of application serial no. 545,656, filed Oct. 26, 1983, now abandoned; which is a continuation-in-part of application serial no. 309,607, filed Oct. 8, 1981, now abandoned (method for producing new varieties of plants). From final rejection of all claims remaining in application, applicant appeals. Reversed.

Ian C. McLeod, Okemos, Mich., for appellant.

Before Steiner, Goolkasian, and Tarring, examiners-in-chief.

Goolkasian, examiner-in-chief.

This is an appeal from the examiner's final rejection of claims 6 through 30, which are all the claims remaining in the application.

Claim 29 is illustrative of the invention and reads as follows:

29. A method for increasing the proportion of altered phenotypes in generations subsequent to at least one progenitor member of a first species of plant, said first species having at least one established phenotype, and said method comprising:

placing said at least one member of said first species in contact with whole cells and associated materials of a second species of plant while simultaneously applying an electrophoretic current across said at least one member of said first species and said whole cells and associated materials of said second species, during a time said at least one member is in a germinal stage; and

allowing said member of said first species to develop from said germinal stage.

The references relied on by the examiner are:

Levengood 3,822,505 Jul. 9, 1974

Janick, *Horticultural Science*, Second Edition, W.H. Freeman and Company, 1963, page 248.

Holl et al. (Holl), *Tissue Culture And Plant Science*, "Genetic Transformation in Plants," Proceedings of the third international congress of plant tissue and cell culture held at the University of Leicester, Leicester, England, July 21-26, 1974, pages 303-306, 308-311 and 320-322.

Appellant's invention is directed to a method for increasing the proportion of mutants in a subsequent generation of a member of a plant species having a recognized and established phenotype. The method involves contacting a member of a first plant species (the recipient) with whole cells and associated materials of a second species (the donor), while the member is in a germinal stage, and simultaneously subjecting the contacted combination to electrophoretic conditions. Appellant believes that mutation occurs via the transduction or migration of genetically associated cell tissue components and macromolecular complexes from the donor (second) species to the recipient (first) species of plant. In a preferred process, the first species of plant comprises corn or tomato and the donor species is Eastern Marsh cabbage root.

All of appellant's claims stand rejected under 35 U.S.C. §103 over Levengood in view of the combined teachings of Janick and Holl. We reverse the rejection.

As noted by the examiner, the Levengood Patent describes a method for increasing the proportion of mutants in a single plant species by applying electrical field gradients to the plant while it is in the germinal stage. Importantly, the Levengood reference does not suggest that members of a first plant species should be placed in contact with whole cells and associated materials of a second species while simultaneously applying the electrophoretic current.

The Janick and Holl references are not concerned with the application of electrical current and merely teach standard grafting and/or genetic engineering procedures. Janick describes the grafting of one type of plant onto the rootstock of another type of plant; for example, fruit trees are grafted onto dwarfing rootstocks in order to produce dwarf fruit trees, and watermelon is grafted onto the gourd *Langenaria* to control Verticillium wilt. This reference has little bearing on what is being claimed. The Holl reference teaches that DNA is capable of being transferred from one species of plant to another, usually by using modified bacteria to infect the plant and incorporate heterologous DNA therein. Importantly, neither Holl nor Janick suggest carrying out their respective processes while simultaneously applying an electrophoretic field.

At pages 4 and 5 of the Answer, the examiner has set forth the rationale for the rejection. The examiner notes that each reference discloses a different aspect of the claimed process. The examiner also notes that all aspects were "well known in the art." The examiner then indicates that because the various aspects of the claimed process were individually known in the art, the modifications of the electrophoretic process of Levengood by exposing Levengood's plant materials to cell-associated materials in order to "graft" or otherwise incorporate the cell associated material into the plants was "*well within the ordinary skill of the art* at the time the claimed invention was made."

We reverse the rejection because the examiner has used the wrong standard of obviousness.

Obviousness is a legal conclusion, the determination of which is a question of patent law. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present *evidence*,[1] preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. See, for example, *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

[1] Motivation for combining the teachings of the various references need not be explicitly found in the references themselves, *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963).[2]

In this case, however, the only suggestion for the examiner's combination of the isolated teachings of the applied references improperly stems from appellant's disclosure and not from the applied prior art. *In re Ehrreich*, 590 F.2d 902, 200 USPQ 504 (CCPA 1979). At best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness. See *Orthokinetics Inc. v. Safety*

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[1] The importance of evidence in the examination process is set forth in the following quotation from *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984):

> The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), focused on the procedural and evidentiary processes in reaching a conclusion under section 103. As adapted to ex parte procedure, Graham is interpreted as continuing to place the 'burden of proof on the Patent Office which *requires it to produce the factual basis for* its rejection of an application under sections 102 and 103'. *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967). After a *prima facie* case of obviousness has been established, the burden of going forward shifts to the applicant.

[2] Preferably the examiner's explanation should be such that it provides that impetus necessary to cause one skilled in the art to combine the teachings of the references to make the proposed modification. *In re Albrecht*, 514 F.2d 1385, 185 USPQ 585 (CCPA 1975). See also *Fromson v. Advance Offset Plate Inc.*, 720 F.2d 1565, 219 USPQ 1137 (Fed. Cir. 1983).

Travel Chairs Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). That which is within the capabilities of one skilled in the art is not synonymous with obviousness. *Ex parte Gerlach*, 212 USPQ 471 (Bd.App. 1980). See also footnote 16 of *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1092, 227 USPQ 337, 343 (Fed. Cir. 1985). That one can *reconstruct* and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.

Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that "would lead" that individual "to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). *In re Newell*, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989). Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done.

In the case before us, the examiner has provided references having teachings which go a long way towards providing a scientific explanation for *what happened* when appellant performed the claimed combination of process steps. However, the references themselves fall far short of providing the "motivation" or "suggestion" to assemble their teachings into a viable process. A *prima facie* case of obviousness has not been made out.

The examiner's rejection of claims 6 through 30 is reversed.

REVERSED.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Phillips

No. 92-3045

Decided April 27, 1993
Released August 6, 1993

PATENTS

1. Practice and procedure in Patent and Trademark Office — Prosecution — In general (§110.0901)

Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Examiner properly shifted burden to patent applicants to establish, through objective evidence, that hybridoma and monoclonal antibody of invention differ in unobvious manner from those of prior art reference, since Patent and Trademark Office lacks facilities and resources to provide factual evidence needed to establish that claimed subject matter is unobvious, and it is thus applicants' burden to make such showing, which requires factual evidence demonstrating that actual, unobvious differences exist, rather than simply speculation about possible differences.

Appeal from final rejection of claims (John Doll, supervisory patent examiner; Robert D. Budens, examiner).

Patent application of Joseph H. Phillips, Lewis L. Lanier, Athena Huey-Jiuan Ding, Elizabeth Evans, David W. Buck, and Lori Rhodes, serial no. 07/146,745, filed Jan. 21, 1988 (Leu 23: monoclonal antibody for monitoring leukocyte activation). From final rejection of all claims remaining in application, applicants appeal. Affirmed.

Robert M. Hallenbeck, Franklin Lakes, N.J., for appellants.

Before Pellman, Goolkasian, and W. Smith, examiners-in-chief.

Smith, examiner-in-chief.

This is an appeal from the final rejection of claims 26 and 27, all the claims remaining in the application. These claims read as follows:

26. A hybridoma deposited as ATCC HB-9627.

27. A monoclonal antibody produced by a hybridoma deposited as ATCC HB-9627.

The reference relied upon by the examiner is:

Hara et al. (Hara), "Human T Cell Activation", *J. Exp. Med.*, Vol. 164, pages 1988-2005 (Dec. 1986).

Claims 26 and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, alternatively, under 35 U.S.C. § 103 as unpatentable over Hara.

We have carefully considered the respective positions of appellants and the examiner and find ourselves in agreement with the position of the examiner. In view of the thorough and complete exposition of the rejection and response to appellants' arguments set forth by the examiner in the Examiner's Answer, we shall adopt the reasoning set forth in the Examiner's Answer as our own and add the following comments for emphasis.

The present invention is summarized in the opening paragraph of the specification as follows:

> This invention relates to a monoclonal antibody (MAb) useful in monitoring leukocyte activation, and more particularly, relates to a monoclonal antibody that will bind Leu 23, an antigen that appears on natural killer (NK) cells, on a subset of low bouyant density (LBD) T lymphocytes rapidly after such cells are activated with Interleukin-2 (IL-2) and on certain T lymphocytes after stimulation of the T cell antigen receptor complex.

[1] Hara discloses a hybridoma which produces a monoclonal antibody which recognizes the EA-1 antigen on activated T cells. Appellants admit on page 2 of the Appeal Brief that the Leu 23 antigen of the present invention and the EA-1 antigen of Hara have been clustered as falling in the CD-69 grouping. Based on this grouping and the similarity in the activated cells on which the respective antigens are found, the examiner has concluded that the respective antigens which are recognized by the monoclonal antibody of the present invention and Hara can reasonably be considered the same or substantially similar. From this, the examiner concluded that it is proper to shift the burden to appellants to establish through objective evidence that the respective hybridomas and monoclonal antibodies do differ in an unobvious manner, citing *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) in support. We agree.

Appellants argue that it is "extraordinarily unlikely" that the two hybridomas and the monoclonal antibodies produced thereby would be the same. In support of this argument, appellants note that different immunogens were used in the present invention and Hara. Appellants also rely upon Knapp[1] as evidence that it is possible to make different antibodies against a single antigen without ever making identical clones. Appellants also argue that their review of the available literature does not indicate that the clone EA-1 of Hara is "commercially available anywhere" and that it is "equally unlikely" that appellants could follow the method disclosed in Hara and duplicate the EA-1 clone since they do not have a comparison product.

Appellants' reliance upon Knapp, at best, indicates that there *might* be a difference between the claimed subject matter and the hybridoma and monoclonal antibody disclosed by Hara. However, we do not find that this in and of itself is a sufficient rebuttal of the rejections. There is no evidence of record which establishes that the respective antigens do, in fact, differ or the significance of such a difference. As set forth in *Best, supra*, the Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there is a difference in the first instance between the respective products, i.e., the claims are directed to new materials, and that such a difference would have been considered unexpected by one of ordinary skill in the art, i.e. the claimed subject matter, if new, is unobvious. This is appellants' burden. Rather than speculate about possible differences, appellants should have presented factual evidence which establishes that actual, unobvious differences exist between the respective materials.

Nor are we persuaded by appellants' arguments that EA-1 is not commercially available and the unlikelihood of them duplicating the work of Hara. Appellants have not placed in this record any evidence which establishes that they communicated with the authors of the Hara reference in an attempt to obtain the relevant material described in their reference. Nor have appellants made of record any evidence setting forth attempts to duplicate the work described in the Hara reference. Attorneys' arguments in an Ap-

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[1] Knapp, "White Cell Differentiation Antigens", *Leucocyte Typing IV*, Oxford University Press, pages 331-337, (1989).